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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SELF-INSURED SCHOOLS OF CALIFORNIA, on behalf of itself and all others similarly situated, Plaintiff, v. **ALLERGAN, INC.**, Defendant.	Case No. **CLASS ACTION COMPLAINT** JURY TRIAL DEMANDED

TABLE OF CONTENTS

Page(s)

TABLE OF CONTENTS (cont.)

Plaintiff Self-Insured Schools of California ("SISC"), on behalf of itself and all others similarly situated, files this Class Action Complaint ("Complaint") against Defendant Allergan, Inc. ("Defendant" or "Allergan"), based upon personal knowledge as to facts pertaining to it and upon information and belief as to all other matters, and alleges as follows:

I. NATURE OF ACTION

1. This civil antitrust action arises from Allergan's scheme to unlawfully prolong its monopoly in the market for prescription cyclosporine ophthalmic emulsion sales in the United States. The Complaint seeks damages on behalf of Plaintiff and proposed classes of end-payors that purchased Restasis® (cyclosporine ophthalmic emulsion) indirectly from Defendant at supra-competitive prices. Plaintiff also seeks injunctive and equitable relief under the United States antitrust laws on behalf of a nationwide class of indirect purchasers.

2. Federal law rewards inventors with a fixed period of patent protection for their novel and non-obvious inventions. But once their legally-sanctioned monopoly ends, the law prohibits patent holders from unlawfully prolonging their monopoly through fraudulent patents, sham proceedings, and collusion. A patent holder may not extend its monopoly by misrepresenting facts to the Patent and Trademark Office ("PTO") to obtain additional blocking patents. It may not sue competitors for alleged infringement of such bogus patents. It may not file baseless petitions with the FDA to exclude competition. And it may not prolong its monopoly by transferring nominal ownership of invalid patents to a sovereign Native American tribe to defeat the jurisdiction of a competent tribunal that is poised to invalidate the patent. Each of these actions, independently and collectively, wrongfully delays generic competition and violates the antitrust laws. Allergan tried all of them to extend its Restasis monopoly.

3. Allergan made approximately $3.3 billion from selling Restasis in the U.S. for eleven-and-a-half years, while it was protected by the U.S. Patent No. 5,474,979 the "'979 Patent" or "Ding I patent"). The PTO issued the Ding I patent in 1995. It expired

on May 17, 2014. Unwilling to cede its monopoly profits to competitors, Allergan devised and executed a multifaceted, anticompetitive scheme to exclude generic competitors from the market. The scheme had the following elements:

4. *Fraud on the Patent Trademark Office*. In the wake of the PTO's repeated rejection of Allergan's efforts to obtain new patents covering Restasis, Allergan resorted to falsely claiming that clinical data showed unexpected effectiveness and surprising test results of its purported inventions. Under applicable patent law, an application for a patent will be rejected by the PTO if the claimed invention is obvious from prior art. By rejecting Allergan's patent applications, the Office established a *prima facie* case of obviousness. To overcome a *prima facie* case of obviousness, the patent applicant has a number of options, including: (i) narrowing the invention to distinguish prior art; (ii) arguing the prior art does not render the claim obvious; or (iii) submitting objective evidence of secondary considerations. Secondary considerations of non-obviousness may be established if the proposed inventions yield unexpected and surprising results. To overcome the PTO's determinations of obviousness, Allergan submitted fraudulent and misleading information to the PTO purporting to show that Allergan's proposed patents experienced unexpected results. Crediting Allergan's misrepresentations, the patent examiner stated that he issued the second-wave Restasis patents (the "second wave patents") because of the unexpected increase in relative efficacy. The PTO was misled: the second wave patents are both obvious in light of prior art and invalid (or otherwise unenforceable) due to Allergan's fraud.

5. *Wrongful Orange Book listing*. Allergan listed the second wave patents in the Food and Drug Administration's ("FDA's") "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Allergan's listing required would-be generic competitors either to delay launching a generic version of Restasis until patent expiry, or to challenge the validity of the second wave patents by making a so-called "Paragraph IV" certification to Allergan, as described below. Allergan's listing of the second wave patents in the Orange Book forced

would-be competitors to file Paragraph IV certifications, which has wrongfully blocked for several years introduction of generic cyclosporine ophthalmic emulsion to compete with Restasis.

6. *Wrongful FDA petitions*. Immediately after improperly listing the second wave patents in the Orange Book, Allergan submitted a series of petitions and comments to the FDA that asked the FDA not to approve generic versions of Restasis unless generic competitors satisfied expensive, time-consuming, and unnecessary conditions that the FDA does not typically impose on drug makers looking to market generic versions of "brand drugs" whose safety and efficacy have already been proven. No reasonable pharmaceutical company in Allergan's position would have expected the FDA to grant the relief that Allergan sought. Indeed, the FDA denied Allergan's various petitions, granting only two requests that asked the FDA to do what it would have done even absent the sham petition.

7. *Wrongful patent enforcement*. Upon receiving paragraph IV certifications from potential generic competitors Actavis (formerly known as Watson, in 2014), and Apotex, Akorn, Teva, and Mylan (all in 2015), Allergan sued each for patent infringement in the Eastern District of Texas. It did this despite knowing that the data the PTO had relied on in issuing the patents was neither new nor unexpected. Each generic manufacturer responded that Allergan's second wave patents were invalid. No reasonable pharmaceutical manufacturer in Allergan's position would have realistically expected to win the litigation. But simply by filing these suits, Allergan guaranteed that its competitors would not get to market for two-and-a-half years.

8. *Conspiracy to monopolize and contract in restraint of trade.* In December 2016, the Patent and Trademark Appellate Board ("PTAB") held, in response to multiple requests for *inter partes* review of the second wave patents, that there was a reasonable likelihood the second wave patents would be invalidated after the PTAB concluded its review. Faced with the reality that the PTAB would invalidate its patents, Allergan entered into a contract in restraint of trade with the Saint Regis Mohawk Tribe (the

"Tribe") to wrongfully perpetuate Allergan's monopoly by transferring ownership of the second wave patents to the Tribe, and then petitioning the PTAB to dismiss its review for lack of jurisdiction (based on the Tribe's sovereign immunity).

9. *Purchasers were injured.* As a result of Defendant's anticompetitive scheme, Allergan earned, to date, an extra $3.9 billion in monopolistic Restasis sales since May 17, 2014—at the expense of the Plaintiff and the proposed classes. In the absence of Defendant's unlawful actions, generic Restasis would have been available by May 17, 2014, and Plaintiff and the proposed classes would have paid less for cyclosporine ophthalmic emulsion products. Plaintiff and the proposed classes have paid hundreds of millions of dollars in overcharges as a result of Defendant's anticompetitive scheme.

II. PARTIES

10. Plaintiff Self-Insured Schools of California ("SISC"), is a Joint Powers Authority under California law that serves the interests of California public school district members. It is headquartered in Bakersfield, California. SISC provides health benefit plans to approximately 300,000 members who reside in numerous locations in the United States. During the Class Period, SISC indirectly purchased and paid for some or all of the purchase price for Restasis, other than for resale, manufactured by the Defendant. During the Class Period, SISC paid and reimbursed more for Restasis than it would have absent Defendant's anticompetitive conduct. As a result of the wrongful conduct alleged herein, SISC was injured in its business or property by reason of the violations of law alleged herein. SISC intends to continue purchasing and/or reimbursing for Restasis and will continue to be injured unless the Defendant is enjoined from its unlawful conduct as alleged herein.

11. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located in Parsippany, New Jersey. During most of the relevant period, Allergan's headquarters were located in Irvine, California, where it still maintains a substantial physical presence. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the

Restasis trademark. Allergan also was the applicant for and holder of each of the six second wave patents which Allergan has claimed cover Restasis: U.S. Patent No. 8,629,111 (dated Jan. 14, 2014); U.S. Patent No. 8,633,162 (dated Jan. 21, 2014); U.S. Patent No. 8,642,556 (dated Feb. 4, 2014), U.S. Patent No. 8,648,048 (dated Feb. 11, 2014), U.S. Patent No. 8,685,930 (dated Apr. 1, 2014), and US 9,248,191 (dated Feb. 2, 2016). As of September 8, 2017, Allergan purports to have transferred its ownership interests in the second wave patents to the Tribe.

12. All of the actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Allergan's officers, agents, employees, or other representatives while actively engaged in the management of Allergan's affairs within the course and scope of their duties and employment, and/or with Allergan's actual, apparent, and/or ostensible authority.

III. JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of the Defendant.

14. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 because Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendant's violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. § 1 and 2. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

15. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1392(b) and (c), because, during all relevant times, Defendant has transacted business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Because Allergan's headquarters were located in Irvine, California during most of the

relevant period, the bulk, if not all, of the challenged conduct was orchestrated, approved, and implemented within this District.

IV. REGULATORY BACKGROUND

A. The Economic Benefits of Blocking or Delaying Generic Entry, Even via Frivolous Patent Proceedings

16. Brand drug companies can, and do, obtain valid patents that cover new prescription drug products.

17. Obtaining a valid patent from the PTO affords brand drug manufacturers a statutory period of time to charge high prices for medications that, in fact, cost relatively little to manufacture. This temporary monopoly stimulates innovation by incentivizing brand drug manufacturers to invest in research and development and to discover important new medicines.

18. Brand manufacturers are required to provide the FDA with information about the patents covering their brand drug products. The FDA, relying completely on the patent information provided by the manufacturer, must then list all patents on a brand drug publicly, so that would-be generic competitors understand the scope of the brand manufacturer's ostensible patent protection.

19. But the brand drug's patent exclusivity period is statutorily limited. Potential competitors can seek FDA approval to sell generic versions of the brand once that statutory period lapses. This allows those companies to manufacture and sell generic versions that are just as safe and effective as, but far less expensive than, the brand.

20. While the patent prosecution process is meant to establish patent rights where the applicant makes the necessary showing to the PTO, the issuance of a patent does not mean that the patent is valid. Many patents issued by the PTO are invalid. That in part because the patent prosecution process is non-adversarial and the PTO must rely on the information provided by the applicant.

21. To help mitigate errors in the patent prosecution process that may result in improvidently issued patents, Congress recently established an "*inter partes* review"

process that empowers the PTAB to review the validity of a previously issued patent. If PTAB determines that the challenger "has a reasonable likelihood of prevailing on at least one of the challenged claims," PTAB is empowered to conduct a trial on the invalidation issues in which the patent holder is the defendant.

22. From this framework, some basic rules emerge. *First*, brand drug manufacturers must deal with the PTO with candor and forthrightness. *Second*, brand drug manufacturers may not provide false or misleading patent or other drug information to the FDA, or use such information to delay entry of less expensive generic medications beyond the expiration of legitimate patent protection. *Third*, brand drug manufacturers may not file a patent infringement lawsuit against would-be competitors when the action has no realistic likelihood of success on the merits, because the mere filing of such a lawsuit delays legitimate efforts to gain market entry. *Fourth*, federal policy favors prompt invalidation of improvidently issued patents; patent holders may not knowingly use invalid patents to harm competition. Allergan broke all these basic rules.

23. Therapeutically equivalent (or AB-rated) generic drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their branded counterparts. The only material difference between generic drugs and brand drugs is their price: when multiple generic drug manufacturer competitors enter the market, generic drugs cost, on average, 80%-85% lower than the branded drug prior to generic entry. Moreover, the Federal Trade Commission (FTC) estimates that within about one year after market entry, a generic drug generally takes over 90% of the brand drug's unit sales.

24. Since the passage of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (the "FDCA"), every state has adopted generic-substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

25. Generic competition enables all members of the proposed Classes to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

26. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and the brand manufacturer can therefore continue to profitably charge supra-competitive prices. Brand drug manufacturers, including Allergan, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers therefore often seek to extend their monopoly for as long as possible and, sometimes, as here, resort to illegal means to do so.

1. Prices plummet when additional AB-rated generics enter the market.

27. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

28. Soon after generic competition enters the market, the vast majority of the unit sales formerly enjoyed by the brand shift to the generic sellers. In the end, the brand manufacturer's revenues decline to a small fraction of the amounts paid before generic entry. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies.

29. There is a predictable pattern to the way brand drug manufacturers develop their patent portfolios. The first group of patents in the brand manufacturer's portfolio for the drug may reflect a genuine technological breakthrough that may later contribute to the success of the drug; these initial "blockbuster" drug patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition and may be correspondingly robust.

30. After filing applications for the original patents, a brand manufacturer typically continues its research and development efforts in the hopes of developing a drug product that could, eventually, be approved by the FDA. As the brand manufacturer's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow-on patents that can be obtained. New patents can be obtained for features of the drugs only if the brand manufacturer can show that the new features are non-obvious distinctions over the growing body of prior art, which includes patents and printed publications, among other things. Often, the initial compound or composition patents disclose methods of using the compounds. And, as the number of patent filings for the drug grows over time, so too does the volume of prior art beyond which the brand manufacturer must show non-obvious distinctions.

31. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a brand drug's active ingredient. If valid and enforceable, these patents may prove impossible to design around while also meeting the FDA's criteria for equivalent generics. Other patents may be less central to the drug, and generic versions of the brand product can sometimes obtain FDA approval and enter the market before all patents expire covering the brand drug expire. In such cases, once all the valid patents covering its blockbuster drug have expired, the brand manufacturer has no lawful means to prevent competitors from entering the market.

32. In short, a typical patent portfolio for a brand drug has its most significant patents issuing first; over time, the later-issued patents generally become increasingly narrow and more difficult to obtain. Even if the narrower coverage is obtained, these later-issued patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious. Moreover, the narrower coverage is more easily designed around by generic drug manufacturers. Because of these design work-arounds, the brand

manufacturer cannot satisfy its burden of proving infringement and thus, cannot keep generics out of the market via non-frivolous patent infringement actions.

2. Because patent prosecutions are non-adversarial, patent applicants are subject to special oaths and duties.

33. Because patents often enable a brand manufacturer to exclude competition and charge supra-competitive prices, it is crucial as a policy matter that any patent underlying a branded drug be valid and lawfully obtained.

34. Patent prosecutions are non-adversarial. Thus, in order to help assure that the public interest is best served though the PTO's issuance of patents that are valid and lawfully obtained, patent applications are subject to various special oaths and duties. This includes the duty of disclosure, candor, and good faith, which requires the applicant to disclose to the PTO of "all information known . . . to be material to patentability," including with respect to prior art. *See* 37 C.F.R. § 1.56. This duty extends not only to each and every named inventor on the patent application, but also to each and every "attorney or agent who prepares or prosecutes the application" and "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id.* at § 1.56(c). No patent may lawfully be granted where fraud on the PTO "was practiced or attempted" or the duty of disclosure, candor, and good faith "was violated through bad faith or intentional misconduct." *Id.* § 1.56(a).

B. New Drug Applications and Patent Listings in the FDA's Orange Book

35. Under the FDCA, drug manufacturers that wish to sell a new drug product must file a New Drug Application ("NDA") with the FDA. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

36. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA then publishes a list of those patents in its publicly available publication *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange

Book." Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand name drug.

37. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the resources or authority to verify the manufacturer's representations for accuracy or trustworthiness and relies completely on the manufacturer's truthfulness about the validity and applicability of any Orange Book-listed patents.

C. Abbreviated New Drug Applications, Orange Book-Related Generic Manufacturer Certifications, and Related Litigation

38. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting a generic manufacturer to file an Abbreviated New Drug Application ("ANDA") with the FDA that may rely on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the blood stream at a similar rate over a similar period of time, are expected to be equally safe and effective.

1. Hatch-Waxman provides an automatic 30-month stay of ANDA approvals to resolve legitimate patent infringement claims.

39. The Hatch-Waxman Amendments created a procedural mechanism to resolve patent disputes between brand and generic manufacturers before generic products are marketed, in the hopes that resolving patent challenges in advance of generic marketing will prevent unnecessary delay. The Amendments permit a brand

manufacturer to sue a generic for patent infringement even if the generic manufacturer has not yet marketed its products.

40. Once one or more patents are listed in the Orange Book, a generic manufacturer seeking FDA approval must certify that the generic drug addressed in its ANDA will not infringe any of those patents. A generic manufacturer can make one of four certifications:

a. That no patent for the brand name drug has been filed with the FDA ("Paragraph I certification");

b. That the patent for the brand name drug has expired ("Paragraph II certification");

c. That the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date ("Paragraph III certification"); or

d. That the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product ("Paragraph IV certification").

41. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can sue the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA cannot authorize the generic manufacturer to begin marketing its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

42. The brand manufacturer can file patent infringement claims more than 45 days after receiving the paragraph IV certification, but doing so would not trigger the automatic 30-month stay of FDA approval.

2. Hatch-Waxman incentivizes generics to challenge questionable patents by awarding 180 days of exclusivity to the first paragraph IV ANDA filer.

43. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an ANDA containing a paragraph IV certification receives 180 days of market exclusivity. This means that other, later ANDA-filers will not be able to market their own generic products for at least six months after the first generic—known as the "first-filer"— begins marketing its product.

44. If the only versions of a drug on the market are the brand and the first-filer's product, then the first-filer prices its product below the brand product, but not as low as if it were facing competition from other generics. Since in these circumstances the first-filer's product may compete only with the brand, and because the brand manufacturer rarely drops the brand price to match the first-filer, the first-filer does not face the kind of price competition that arises when additional generic competitors enter the market.

D. The Citizen Petition Process

45. Section 505(j) of the FDCA creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a "citizen petition."

46. Citizen petitions provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product before, or after, its market entry.

47. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part, or to deny the request. The

Commissioner also may provide a tentative response with an estimate on a time for a full response.

48. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because the FDA must research the petition's subject, examine scientific, medical, legal and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources.

49. The FDA's longtime practice—well-known in the pharmaceutical industry—had been to withhold ANDA approval until it completed its consideration of, and response to, a citizen petition regarding that ANDA. The former director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research ("CDER") acknowledged that it was "very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

50. For more than a decade, a number of brand manufacturers have abused the citizen petition process, using it as a tactic to extend their monopolies on their branded drugs when faced with entry by generic competitors. Citizen petitions filed by brand manufacturers rarely raise legitimate concerns about the safety or efficacy of generic products, and instead only seek to preserve monopolies after the end of a statutorily-granted patent or FDA exclusivity period. The timing of these tactical filings is important: brand manufacturers frequently file these citizen petitions on the eve of FDA approval of an ANDA for competing AB-rated generic drugs, even though the petitioner could have made the same arguments months, or even years, before. This results in delay of approval (tentative or final) of a pending ANDA for several months (or more) while the FDA evaluates the merits of the citizen petition.

51. The resulting delay of generic competition can be lucrative for an incumbent brand manufacturer facing impending competition from an AB-rated generic.

The cost of filing a baseless citizen petition pales in comparison to the value of securing an additional period of monopoly profits.

52. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last 15 years, as brand manufacturers have sought to compensate for dwindling new product pipelines. In some such cases, citizen petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand manufacturer received notice of the ANDA filing, and have had the effect of delaying the approval of the generic product.

53. The FDA has long acknowledged citizen petition abuse, stating as far back as 2005 that it had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try [to] delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

54. The abuse of the citizen petition process in part helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. 355(q) (the "FDAAA"), which added new section 505(q) to the FDCA, providing that the FDA shall not delay approval of a pending ANDA because of a citizen petition unless the FDA determines that a delay is necessary to protect the public health. The FDAAA does not, however, provide the FDA with additional resources that might allow it to more promptly respond to citizen petitions, meaning that a brand manufacturer can still use the citizen petition process to delay generic approval while the FDA considers whether the citizen petition implicates issues of public health, regardless of whether the petition has any real merit.

55. Years after the enactment of the FDAAA, the FDA continues to have serious concerns about the abuse of the citizen petition process for anticompetitive purposes, noting in a 2012 report to Congress that "based on the petitions that FDA has seen to date . . . the agency is concerned that section 505(q) may not be discouraging the

submissions of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products." Indeed, recent studies have found that many citizen petitions from brand manufacturers "appear to be last-ditch efforts to hold off generic competition," and that between 2011 and 2015, the FDA denied 92% of section 505(q) citizen petitions, which are the type most often used—like Allergan did here—to delay generic entry. *See* Feldman, *et al.*, *Empirical Evidence of Drug Pricing Games – A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 70 (2017); Carrier & Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305, 332-333, Table 4 (2016).

E. Proceedings Before the Patent Trial and Appeal Board

56. In 2011, Congress passed the Leahy-Smith America Invents Act to address a widely-held concern that invalid patents were being issued and enforced, to the detriment of both innovation and the economy. A centerpiece of the Act was the creation of new "*inter partes* review" ("IPR") proceedings, by which members of the public could challenge improperly-issued patents and have them eliminated much more quickly and inexpensively than through expensive and time-consuming patent litigation. IPR proceedings also bore the promise of a review by technically-educated members of the PTAB who are deeply familiar with the science at issue in any particular proceeding.

57. The Act allows the PTAB to review existing patents and extinguish those rights in an adversarial trial process. An IPR commences when a party—often an alleged patent infringer—petitions the PTAB to reconsider the PTO's issuance of an existing patent and invalidate it on the ground that it was obvious or anticipated by prior art.

58. The PTAB will grant a request for an IPR only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The PTAB must decide the review within one year of the initiation date.

59. The PTAB trial proceedings have become an exceedingly effective method of challenging improperly-granted patents—at least 84 percent of patents reaching a final

written decision in PTAB validity challenges are adjudicated to have at least one invalid claim, and 69 percent have had *all claims* cancelled as invalid. *See* Steve Brachmann & Gene Quinn, *Are more than 90 percent of patents challenged at the PTAB defective?* IPWatchdog (June 14, 2017).

V. FACTUAL ALLEGATIONS

A. The FDA Approves Restasis

60. Allergan manufactures and sells the prescription drug cyclosporine under the brand name Restasis, an emulsion consisting of various components, including the active ingredient cyclosporin A, an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride. Restasis is used to treat a condition called "dry eye," which is caused by the failure to produce tears in the normal fashion. Restasis is one of the most widely prescribed drugs in the world; last year, in the United States alone sales of Restasis were nearly $1.5 billion.

61. In 1993, Allergan licensed from Sandoz, Inc., the technology of treating aqueous-deficient dry eye with cyclosporine. That technology was the subject of U.S. Patent No. 4,839,342 to Kaswan ("the '342 patent" or "the Kaswan patent"). The Kaswan patent claimed methods for enhancing or restoring lacrimal gland tearing comprising topically administering cyclosporine to the eye in a pharmaceutically acceptable vehicle, in this case topical administration. The Kaswan patent also recited the use of castor oil, among other compounds, as a pharmaceutically acceptable vehicle for delivering cyclosporine to the eye.

62. Because cyclosporine is highly insoluble in water, Allergan had to develop an oil-in-water emulsion castor oil (a hydrophobic vehicle that would dissolve the cyclosporine), together with an emulsifier and an emulsion stabilizer in water. Allergan disclosed this work in two patents, the first of which was U.S. Patent No. 5,474,979 ("the '979 patent" or "the Ding I patent"), which issued in 1995. The Ding I patent contained four examples, the first two of which contained multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to

0.40% cyclosporine and 0.625% to 5.00% castor oil. The Ding I patent stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the more preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12. The formulation for Restasis falls within the range of values disclosed and claimed in the Ding I patent.

63. The second patent, U.S. Patent No. 5,981,607 ("the '607 patent" or "the Ding II patent"), is entitled "Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers." The Ding II patent disclosed and claimed a method of alleviating dry eye related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, all without cyclosporine.

64. Allergan then began clinical trials of various combinations of cyclosporine and castor oil. In the first clinical trial (the "Phase 2" study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriate dosage (*e.g.*, 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). The results were published in the periodical article Dara Stevenson *et al.*, *Efficacy and Safety of Cyclosporine A Ophthalmic Emulsion in the Treatment of Moderate-to-severe Dry Eye Disease, A Dose-Ranging, Randomized Trial*, 107 Ophthalmology 967 (May 2000). The study concluded that all tested concentrations significantly improved the ocular signs and symptoms of moderate-to-severe dry eye disease, and mitigated dry eye disease's effects on vision-related functioning. All tested concentrations were safe and effective in increasing tearing in certain patient groups.

65. Notably, Stevenson concluded that there was no clear dose-response relationship between the 0.05% cyclosporine formulation and the formulations containing greater amounts of cyclosporine—efficacy did not increase with increases in dosage amounts. However, the 0.1% cyclosporine formulation "produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining)," while the 0.05% cyclosporine formulation "produced the

most consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness)." *Id.* at 974. Therefore, Stevenson's study suggested that "subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations." *Id.*

66. Phase 3 trials did just that, with the results published in Kenneth Sall *et al.*, *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000). Phase 3 confirmed the results of Phase 2, and found the 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, though castor oil alone also produced significant improvements over the patient's baseline, suggesting that it was a contributing factor to the formulations' success.

67. Statistically, there was no significant difference between the 0.05% cyclosporine formulation and the 0.1% formulation in either Phase 2 or 3.

68. Following the Phase 3 study, Allergan filed a NDA seeking authorization to market the 0.05% cyclosporine product that was tested in the Phase 3 trials. The proposed commercial product, which is Restasis, would contain all the components of the Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil. The FDA approved the application in December 2002, authorizing the sale of Restasis for the following indication: "Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs." Since its initial marketing in 2003, Restasis has been a highly successful product.

B. Allergan Prosecutes Serial Patent Applications to Extend the Restasis Monopoly

1. The PTO repeatedly rejects Allergan's serial efforts to obtain additional patents for "new" combinations of castor oil and cyclosporine that were obvious in light of prior art.

69. For over a decade following the FDA's approval of Allergan's Restasis NDA, Allergan filed a variety of patent applications, attempting to obtain patents on

combinations of castor oil and cyclosporine, notwithstanding the earlier published work that already claimed a broad range of combinations, with no statistically different outcomes based on the particular combination. Among others, Allergan filed U.S. Patent Application No. 10/927,857 ("the '857 application") on August 27, 2004. The '857 application and dependent claims were again based on combinations of cyclosporine and castor oil within the range covered by Ding I. Allergan withdrew a number of the claims of the '857 application, and, unsurprisingly, the PTO examiner rejected the remaining claims based in part on obviousness in light of the Ding I patent.

70. Allergan then amended the '857 application in 2007 to include a claim to an emulsion comprising water, 1.25% castor oil, and 0.05% cyclosporine, which is the percentage of those components in Restasis. As would be expected, the PTO examiner again rejected the application. Allergan appealed and in 2007, while the appeal was pending, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177 application"). The '177 application was similar to the '857 application, but it added claims regarding new conditions that the method was asserted to treat, including corneal graft rejection.

2. In 2009, Allergan concedes that its "new" cyclosporine/castor oil combination claims are obvious in light of Ding I.

71. In June 2009, Allergan contradicted its earlier patentability claims, and conceded, with respect to both the '857 and '177 applications that the various composition claims were obvious in light of Ding I. Allergan explained, in writing, that it "concede[d] that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant." Allergan, in its own words, "concede[d] that in making this selection (0.05% cyclosporine and 1.25% castor oil) there would have been a reasonable expectation of success; the differences between Examples 1A-1E and [the Restasis formulation] are too small to believe otherwise." According to Allergan, the composition claims advanced

by the ’857 and ’177 applications were “squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise, whether in [either the ’857 or ’177 applications].” Allergan withdrew its then-pending appeal.

72. After cancelling the previous claims on the ’857 application, Allergan tried once more to add to it a new claim regarding another composition of cyclosporine and castor oil. As with all the other composition claims, the PTO examiner rejected the new composition claim as obvious in light of Ding I (and for non-statutory double patenting over Ding I). By April 2011, a notice of abandonment was entered on the ’857 application. The ’177 application ultimately issued as U.S. Patent No. 8,618,064, but was narrowly limited to only the additional use for the treatment of corneal graft rejection.

3. Facing the imminent May 2014 expiration of Ding I, in August 2013, Allergan files a series of new continuation applications, all deriving from the ’177 application.

73. Having repeatedly failed to convince the PTO to grant patent protection over various “new” composition claims, and with the May 2014 expiration of Ding I on the immediate horizon, in August 2013, Allergan filed six additional continuation applications deriving, directly or indirectly, from the ’177 application. These six additional applications were identical with only minor variations, modifying the prior specifications by adding four sentences that further described the role of cyclosporine as an immunosuppressant and the conditions that can be treated with cyclosporine. As the Eastern District of Texas later found in invalidating the patents that subsequently issued from these applications, “[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and KCS after the expiration of the Ding I patent in 2014.” *Allergan, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455, ECF No. 523 at 20 (E.D. Tex. Oct. 16, 2017) (hereinafter, “Invalidation Decision”).

74. In initiating these 2013 applications, Allergan tried to claw back its prior concession that various cyclosporine-castor oil combinations were obvious in light of Ding I, claiming to have new data supporting patentability, based on "unexpected" results showing the claimed Restasis formulation to be particularly effective. The PTO again rejected the claims presented by the 2013 applications as obvious in light of Ding I.

75. Responding to that rejection, Allergan submitted declarations executed in October 2013 from two of its scientists, demonstrating, according to Allergan, that the Restasis formulations reflected in the 2013 applications outperformed other combinations to a "surprising" extent not anticipated by Ding I and other prior art. Specifically, Allergan represented to the PTO examiner that Dr. Schiffman's declaration demonstrated surprising test results, namely:

> [T]he claimed formulation [of 0.05% cyclosporin and 1.25% castor oil] demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan's Phase 3 trials compared to the relative efficacy for the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation discussed in Example 1E of Ding, tested in Phase 2 trials. The data presented herewith represents the subpopulation of Phase 2 patients with the same reductions in tear production (x 5mm/5 min) as those enrolled in the Phase 3 studies. . .. Exhibits E and F also illustrate that the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation tested in Phase 2 and disclosed

in Ding (Ding 1E). This was clearly a very surprising and unexpected result.

76. On the basis of Allergan's representation of Dr. Schiffman's discovery and the declaration itself, the PTO examiner reversed course. The examiner stated that the Schiffman declaration "is deemed sufficient to overcome the rejection . . . based on [Ding I] . . . because . . . Examiner is persuaded that, unexpectedly, the claimed formulation . . . demonstrated an 8-fold increase in relative efficacy . . .." The Examiner allowed the patents to issue with respect to all six applications, which issued in early 2014 as U.S. Patent Nos. 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), 8,685,930 ("the '930 patent"), and in 2016 as U.S. Patent No. 9,248,191 ("the '191 patent"). These are the second wave patents at issue here.

4. Allergan's 2013 data and results were neither new nor unexpected, and fraudulently induced the PTO to grant the second wave patents.

77. In reality, however, the statements and data reflected in Dr. Schiffman's declaration that Allergan represented to the PTO examiner as presenting new and unexpected results were not new. Instead, Dr. Schiffman's declaration consisted of statements plagiarized from an article published thirteen years earlier in a well-known medical journal,[1] which article had itself relied on Allergan's very own Restasis Phase 3 clinical trial data from the 1990s. *See* Sall *et al.*, *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000) ("Sall Article"). In fact, this was the very publication that publicized Allergan's Phase 3 clinical results.

[1] Sall, et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000) ("Sall Article").

78. Not only was the "new" 2013 data not new, it did not demonstrate unexpected results. As the Eastern District of Texas found (*see* Invalidation Decision at 133), Allergan's presentation to the PTO substantially overstated the difference between the clinical results obtained with the Ding formulations and the clinical results obtained with the Restasis formulation. The actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent.

79. In submitting the 2013 continuing applications, Allergan sought new patent protection on substantially the same claims the PTO examiners had rejected on numerous prior occasions. These "new" claims were also negated by Allergan's concession in 2009 of obviousness in light of prior art. The PTO examiners granted these claims only upon reliance on Allergan's Schiffman Declaration and Allergan's false assertions of "new" data and "surprising" results.

80. Allergan made these representations and characterizations, both by commission and omission, with the intent to deceive the PTO, and such representations and characterizations were material and fraudulently induced the PTO to grant the second wave patents. As the Eastern District of Texas later found:

> To the extent that Allergan relies on Dr. Schiffman's presentation to the PTO . . . and the fact that the examiner concluded that unexpected results had been shown . . . the Court finds that the presentation made to the examiner in 2013, including Dr. Schiffman's declaration and the accompanying exhibits, painted a false picture of the comparative results of the Phase 2 and Phase 3 trials. In addition, that presentation created the misleading perception that the evidence that Dr. Schiffman relied on to show unexpected results was not known at the time of the invention. Accordingly, the Court regards the examiner's finding of

unexpected results to be entitled to no weight, based as it was on evidence that did not accurately depict the comparative results of the two Allergan studies and that was, in any event, disclosed in the prior art.

81. Had Allergan made clear to the PTO examiner that the Schiffman Declaration statements and data were lifted from prior art known to Allergan for over 10 years, as its Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected the 2013 applications for the same reasons it had repeatedly denied every other prior application: the claims presented were obvious in light of the prior art.

C. Allergan Wrongfully Lists Its Invalid Second Wave Patents in the Orange Book, Creating Confusion and Delay in the ANDA Approval Process and Setting Up Sham Patent Infringement Suits Against Generic Competitors to Further Delay Generic Entry.

82. The second wave patents issued beginning on January 14, 2014, starting with the '111 patent, which Allergan immediately listed in the Orange Book. This listing required any ANDA filer seeking to market generic Restasis to file a certification as to that "new" patent.

83. The FDA has acknowledged, however, that shortly before the issuance of the '111 patent, the agency had received at least one ANDA for generic Restasis. Up until the listing of the second wave patents, ANDAs may have been filed with paragraph II and/or III certifications, which meant that the generic would not be marketed until after expiration of Ding I in May 2014, then just months away. Without Allergan's machinations, any paragraph II and/or III certified ANDAs would have been unhindered by any patents or citizen petitions, resulting in approval of generic Restasis as early as May 17, 2014 (and in any case, within the class period), and generic competition to Restasis would have created immediate benefits to Plaintiff and the proposed Classes in the form of lower prices.

84. Instead, all prior ANDA filers now had to amend their ANDAs to include paragraph IV certifications with respect to the '111 patent (and eventually the other

second wave patents). Worse, the confusion Allergan created by its eleventh-hour patent applications and Orange Book listings meant that the order in which the FDA received any prior ANDA certifications likely was different than the order in which the agency received the paragraph IV certifications with respect to the second wave patents, creating various first-filer status uncertainties.

85. The wrongful Orange Book listings had another immediate impact: they effectively required all ANDA applicants to file paragraph IV certifications with respect to the second wave patents, which thereby enabled Allergan to sue for infringement and trigger the automatic 30-month stay of FDA approval. In contrast, paragraph II or III-certified ANDAs are not subject to that stay.

86. Allergan knew when it listed the second wave patents in the Orange Book that such patents were invalid but nevertheless would provide Allergan a basis to delay generic competition to Restasis beyond May 2014 and otherwise would create confusion that would further chill the FDA's ANDA approval process.

D. One or More ANDA Applicants Would Have Been Ready, Willing, and Able to Manufacture and Distribute Commercial Quantities of Generic Restasis in May 2014 upon Expiration of Ding I.

87. Beginning in 2011, and continuing in 2012 and thereafter, numerous pharmaceutical manufacturers—including some of the biggest brand and generic pharmaceutical manufacturers in the world—submitted ANDAs seeking the FDA's approval to market generic Restasis. But for Allergan's misconduct as alleged herein, one or several of these ANDA filers would have received FDA approval and would marketed the commercial quantities of generic Restasis necessary to supply the market upon expiration of Ding I in May 2014. Other ANDA applicants would have been ready after May 2014 but earlier than they were under Allergan's anticompetitive scheme.

88. The long list of generic manufacturers that to date have filed ANDAs seeking to market generic Restasis include Watson, Teva, Mylan, Akorn, Apotex, Innopharma (Pfizer subsidiary), Famy Care, Twi Pharmaceuticals, and Deva Holding.

But for the resource-drain, confusion, and administrative delays experienced by FDA and Restasis ANDA filers resulting from Allergan's improper Orange Book listing, citizen petitions, and/or patent suits, some or all of these generic competitors would have been approved and on the market beginning as early as May 2014.

89. The existence of multiple Orange Book-listed patents, multiple citizen petitions concerning complicated generic approvability standards, ongoing patent litigation, and especially the combination of the foregoing, can act as a disincentive for generics considering whether and when to aggressively pursue submission and/or approval of a particular ANDA. The process of contesting even baseless (but complicated) legal or scientific assertions necessarily adds to the time and resources required for the generic approval process, both with respect to the ANDA applicants seeking generic approval and the FDA in reviewing those applications, all of whom must set priorities to allocate limited resources.

90. ANDA filers are less likely to aggressively pursue the filing or approval of ANDAs when faced with these added hurdles and complications, and the FDA has fewer resources available for legitimate scientific research when it is forced to respond to a series of extensive but baseless citizen petitions. Moreover, the FDA has policies to prioritize or expedite review of ANDAs that otherwise have a clear path to market (as would have been the case for Restasis ANDAs as of May 2014 were it not for Allergan's fraudulently obtained patents and wrongful petitioning).

91. The Restasis ANDA filers had no choice but to contend with the resulting hurdles. As Mylan's CEO Heather M. Bresch stated in Mylan's November 3, 2017 earnings call, "I think this is a great example of [Mylan] persevering through what I would call [Allergan's] pretty desperate legal maneuvers to try to maintain a monopoly that should have been gone a couple of years ago, and our ability continue to fight not only in the courts, but with the science and have a clear pathway to approvals."

92. Had scientists, regulatory professionals, and lawyers at Mylan, other generic manufacturers, and the FDA not been tied up by Allergan's "desperate legal

maneuvers," and had they not been forced for years to "continue to fight" Allergan's anticompetitive conduct, they would have remained focused solely on ensuring that safe and effective generic versions of Restasis were approved "years ago" at, or as near as possible to, the expiration of the '979 patent in May 2014. This delay in competition is exactly what Allergan intended to, and did, cause through its unlawful scheme.

E. Allergan Files Sham Patent Infringement Suits to Delay Generic Entry

93. In response to Allergan's Orange Book listings, and exactly as Allergan had planned, generic competitors provided paragraph IV certifications with respect to the second wave patents. Generic manufactures Apotex, Akorn, Mylan, and Teva all submitted paragraph IV certifications within weeks of each other starting in July 2015, asserting that the second wave patents either were invalid or non-infringed. Because the patents were procured by fraud and otherwise invalid as obvious in light of Ding I and other prior art, Allergan had no legitimate basis to enforce them. Yet Allergan responded to each of the above paragraph IV certifications from potential generic competitors by filing multiple patent infringement actions, beginning on August 24, 2015.

94. These infringement suits triggered the automatic 30-month stay of any FDA final approval of ANDAs filed after the second wave patents were listed.

95. On October 16, 2017, after trial in August, the Eastern District of Texas found the second wave patents invalid based on obviousness. In a thorough 135-page post-trial Findings of Fact and Conclusions of Law, the court found that Allergan had secured these Patents "by way of a presentation that was more advocacy than science." *See* Invalidation Decision at 133. The court found particularly compelling the 2009 concessions, the fact that Allergan's "unexpected" results were foreseeable based on the early cyclosporine studies, and that in any event, the "new" Restasis formulation claimed by the second wave patents had statistically the same efficacy as one of the prior art examples in Ding I.

96. The court also dismissed other arguments Allergan made at trial (*see* Invalidation Decision at 134-35), including assertions that the "surprising" results arose

from a difference between the Phase 2 and 3 studies, and that there were objective, valid reasons for issuing new patents:

> While Allergan has pointed to evidence of objective considerations such as commercial success and long-felt unmet need, the force of that evidence is considerably blunted by the fact that, based on protection from a succession of patents, Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014. And the issuance of the [second wave] Restasis patents has barred any direct competition for Restasis since then. The evidentiary value of the objective consideration evidence has thus been considerably weakened by the existence of blocking patents during the critical period.

97. Allergan brought these multiple infringement suits, regardless of any objective merit. Indeed, Allergan had conceded in 2009 that the claims in the '857 and '177 applications (the basis for what issued as the second wave patents) were obvious in light of Ding I, and Allergan knew it had obtained the second wave patents only through its fraudulent misrepresentations to the PTO. Accordingly, there never was any objective merit to any of these infringement suits.

98. The objective merits were irrelevant, however, to Allergan's true purpose. Allergan filed those suits not to vindicate any legitimate patent infringement issues but to improperly use governmental process and the workings of the Hatch-Waxman Act to delay generic competition to its Restasis monopoly. If it filed even the most baseless of patent infringement suits, Allergan knew it would still obtain and immediately benefit from the automatic 30-month stay of FDA final approval of any generic Restasis product. For a $1.5 billion/year franchise, every extra month Allergan could postpone competition from generic Restasis added another $125 million to its revenues.

F. Allergan Abuses the FDA's Citizen Petition Process to Delay Generic Entry

99. Another prong of Allergan's multifaceted scheme was to delay the FDA's approval of any Restasis ANDA by hijacking the agency's citizen petition process.

100. Allergan's citizen petitions related to the FDA's June 2013 nonbinding draft guidance giving Restasis ANDA applicants two options to demonstrate the bioequivalence necessary to secure FDA ANDA approval. Pursuant to the June 2013 draft guidance to establish the bioequivalence of generic Restasis with its branded counterpart, Restasis ANDA applicants could use one or both of: (1) in vivo testing (*i.e.*, testing performed on live humans, often referred to as "clinical endpoint studies"); or (2) in vitro testing (*i.e.*, a test tube). Generic drug makers typically use in vitro testing in their ANDAs to demonstrate bioequivalence with a branded drug, because it is cheaper and less time-consuming than the in vivo clinical trials that brand manufacturers generally must undertake in support of their original NDA, studies that the FDA believes "may present economic and logistical challenges for ANDA sponsors."

101. Allergan gave the FDA its views on the draft guidance in a lengthy comment submitted to the agency in August 2013, asserting that the FDA could not approve any Restasis ANDA relying on in vitro testing and asking the FDA to "replace the Draft Guidance with a revised guidance document that explains in vivo comparative clinical studies are required to demonstrate that a proposed generic product is bioequivalent to" Restasis. Allergan's criticism of the draft guidance was echoed by comments submitted by several doctors who, unbeknownst to the FDA, had in 2013 received payments of up to $70,000 from Allergan for "consulting" on Restasis. The FDA typically publishes its responses to the public comments received in response to its draft guidance, but is not required (like it is with a citizen petition) to formally respond to individual requests to take (or refrain from taking) action.

102. Despite having aired its criticism of the FDA's draft guidance during the August 2013 comment period, Allergan nonetheless began inundating the FDA with

citizen petitions immediately following its improper listings in the Orange Book. While Allergan asserted that its citizen petitions were submitted to tell the FDA that "rushing prematurely to approve a proposed generic drug [not supported by in vivo clinical endpoint studies] poses a risk to patient health," Allergan's true goal was to delay the FDA's review of any Restasis ANDAs by saddling the agency with baseless, duplicative citizen petitions relating to the 2013 draft guidance—a tactic that Allergan told investors exemplified its response to "intense competition from generic drug manufacturers."

103. Allergan submitted its first citizen petition on January 15, 2014, which was superseded by another citizen petition filed on February 28, 2014 (the "February 2014 Citizen Petition"). The February 2014 Citizen Petition largely parroted its public comments to the FDA in August 2013. Among the February 2014 Citizen Petition's six requests—each of which required a formal, time-consuming response from the FDA within 180 days—Allergan asked that the FDA "make clear that the only way to demonstrate bioequivalence to Restasis is through comparative clinical endpoint studies [*i.e.*, in vivo]," and "refus[e] to accept or approve any [Restasis] ANDA if it does not include data from one or more appropriately designed comparative clinical trials to demonstrate bioequivalence." The February 2014 Citizen Petition cited to the public comments submitted by its cadre of paid doctors, ostensibly "draw[ing] from their clinical experience, criticizing the draft guidance's in vitro approach."

104. On November 20, 2014, the FDA largely rejected the requests in the February 2014 Citizen Petition. It explained that the in vitro-only option in its June 2013 draft guidance was consistent with "the Agency's authority to make bioequivalence determinations on a case-by-case basis using in vivo, in vitro, or both types of data," which enabled the FDA "to effectuate several long-standing policies that protect the public health" when approving ANDAs for generic drugs.

105. The FDA then explained that with respect to "locally acting, non-systemically absorbed drug products" like Restasis, the in vivo studies urged by Allergan's citizen petition were "usually of limited utility," noting that while its 2013

draft guidance for Restasis ANDAs had recommended using either in vivo or in vitro studies, the "modest efficacy demonstrated by Restasis" meant that an in vivo bioequivalence study "may not be feasible or reliable." The November 20, 2014 letter then explicitly rejected Allergan's request that Restasis ANDAs based on in vitro bioequivalence studies be rejected, telling Allergan that the FDA concluded that "an in vitro study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence" for generic Restasis.

106. The FDA's rejection of the February 2014 Citizen Petition did not dissuade Allergan from its efforts to further delay generic competition for Restasis by abusing the citizen petition process. Allergan submitted a second citizen petition on December 23, 2014 (the "December 2014 Citizen Petition"), which consisted largely of repetitions of the arguments in the February 2014 Citizen Petition. Allergan supplemented the December 2014 Citizen Petition four times, including an August 16, 2015 supplement in which Allergan requested (among other things) that the FDA convene a committee of outside experts to evaluate the use of in vitro methods for generic Restasis, and that the FDA refuse to receive, review or approve any Restasis ANDAs until that outside evaluation was complete.

107. The FDA rejected the December 2014 Citizen Petition and its many supplements, stating in its February 10, 2016 response that the December 2014 Citizen Petition "repeat[ed] many of the assertions that were at the center of Allergan's previous petition," and declined to repeat the agency's detailed answers from its November 20, 2014 response to the February 2014 Citizen Petition. The FDA nominally granted two of Allergan's minor requests, but they did not change the FDA's practice. In the absence of Allergan's petitions the FDA would have taken those requested actions anyway.

108. The February 10, 2016 letter again expressed the FDA's doubts about the in vivo studies that Allergan urged as requirements for any Restasis ANDAs, and noted that the claims in the December 2014 Citizen Petition "lack legal support" and "rest on

flawed logic." Despite the FDA's misgivings about the lack of sound, substantive bases for Allergan's citizen petitions, the FDA was nonetheless obligated to specifically respond to each of Allergan's requests, and informed Allergan in the February 10, 2016 letter that FDA would "not approve or receive any ANDA referencing Restasis based on in vitro assays unless and until FDA responds specifically to the findings of Allergan's testing of nine experimental test emulsions" submitted with the December 2014 Citizen Petition. In other words, the FDA delayed approving any Restasis ANDA because of Allergan's serial citizen petition campaign. But Allergan's characterization of its purported findings are no less baseless than the other aspects of Allergan's sham serial citizen petitions. The FDA will reject them in due course.

G. Allergan Enters a Sham Agreement with the Saint Regis Mohawk Tribe in a Naked Attempt to Avoid PTAB Invalidation of the Second Wave Patents

109. Allergan's latest effort to forestall generic competition to Restasis stems from a series of IPR requests. In June 2015, Apotex, which subsequently provided Allergan notice of its second wave patent paragraph IV certifications on July 23, 2015, was the first ANDA applicant to petition the PTAB to initiate an IPR review of the second wave patents. Allergan settled the Apotex IPR proceedings in December 2015, on undisclosed terms, just days before the PTAB was set to determine the likelihood that the PTAB would invalidate the second wave patents. The terms of Allergan's settlement with Apotex have not been made public, so Plaintiff presently is unable to determine whether that settlement may have included a large and unjustified payment from Allergan to Apotex and thus constitute yet another component in Allergan's unlawful scheme. *See FTC v. Actavis*, 133 S. Ct. 2223 (2013); *In re Cipro Cases I & II*, 61 Cal.4th 116 (2015).

110. By December 2015, other ANDA applicants, including Mylan and Teva, had also petitioned the PTAB for IPR proceedings on the second wave patents. In December 2016, the PTAB resolved the same question that the Allergan settlement with

Apotex mooted the year before, concluding that there was a reasonable likelihood that each of the second wave patents would be invalidated upon the PTAB's further review and thereby instituted proceedings against all six of the second wave patents.

111. On September 8, 2017, Allergan entered into an agreement to convey ownership of the second wave patents to the Tribe, with an exclusive license back to Allergan for "all FDA-approved uses in the United States" and a promise not to waive the Tribe's sovereign immunity with respect to any IPR or other administrative action in the PTO related to the patents. The agreement provided for Allergan to pay the Tribe $13.75 million, plus potentially an additional $15 million in annual royalties. On September 22, 2017, after the Tribe and Allergan agreed to this unlawful transfer of property rights, Allergan, using the Tribe as a conduit, petitioned the PTAB to dismiss the remaining pending IPRs for lack of jurisdiction based on tribal sovereign immunity.

112. The trial court in the Eastern District of Texas in the infringement case which Allergan recently lost agreed to join the Tribe as a co-plaintiff, but only as a hedge to ensure that any judgment it rendered would apply to the Tribe as well. The court explained that despite its "serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed," it would "adopt the safer course of joining the Tribe as a co-plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings, where it is directly presented." *See Allergan, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.,* No. 2:15-cv-01455, ECF No. 522 at 4, 9 (E.D. Tex. Oct. 16, 2017).

113. The Judge presiding over the district court case is the Honorable William C. Bryson, who is a Circuit Court Judge for the United States Court of Appeals for the Federal Circuit, and was sitting by designation within the Eastern District of Texas. The Federal Circuit has exclusive jurisdiction over appeals within patent infringement cases. Judge Bryson observed that if Allergan's ploy was successful, then that "could spell the end of the PTO's IPR program, which was a central component of the America Invents

Act of 2011." Judge Bryson also observed that "Allergan is conspicuously silent about the broader consequences of the course it has chosen." Judge Bryson continued:

> [S]overeign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities. It is not an inexhaustible asset that can be sold to any party that might find it convenient to purchase immunity from suit. Because that is in essence what the agreement between Allergan and the Tribe does, the Court has serious reservations about whether the contract between Allergan and the Tribe should be recognized as valid, rather than being held void as being contrary to public policy.

114. Judge Bryson also questioned whether the Tribe acquired sufficiently substantial rights in the transferred patents to be deemed the actual owner of the patents. As part of the transaction, the Tribe purchased the patents subject to certain terms and conditions, and the Tribe subsequently granted an exclusive license back to Allergan. Judge Bryson observed, "[e]ven assuming that the initial assignment was valid, the Tribe would not be considered the owner of the patents if, through the exclusive license agreement, it has transferred all substantial rights in the patents except for the right to receive royalties on the sale of Restasis." Under the terms of the transfer, the Tribe retained the right to practice and use the patents for "research, scholarly use, teaching, education, patient care incidental to the foregoing, sponsored research for itself and in collaborations with Non-Commercial Organizations ('Non-Commercial Uses') . . . ." (Patent License Agreement between the Tribe and Allergan ("Patent License Agreement"), dated September 8, 2017, ¶ 2.4). Judge Bryson observed that it is "questionable whether those rights have any practical value." Indeed, if taken at its word, the Tribe presumably already had the right to practice and use the patents in these ways given that it could previously have asserted sovereign immunity against any suit for

infringement on these grounds. Thus, any purported rights in the patents actually gained by virtue of the transfer are illusory. The Tribe also retained the right to sue for infringement of the patents unrelated to generic equivalents of Restasis®. (Patent License Agreement, ¶ 5.2.3). Yet, this right was equally illusory because the Tribe simultaneously agreed to refrain from developing, marketing or licensing any product for an indication that is the same or includes one for which Restasis® has been approved. (Patent License Agremenet, ¶ 2.4, ¶ 1.10). Thus, any infringement suit for the patents commenced by the Tribe, under the terms of its agreement with Allergan, would be nugatory to the extent the Tribe would necessarily lack the right to license those for any practical use.

115. Allergan has made no secret of its subjective bad faith in seeking to add the Tribe as a defendant in the IPRs. Allergan's chief executive, Brent Saunders, explicitly acknowledged that Allergan pursued the deal with the Tribe not to advance competition on the merits, but rather to avoid "double jeopardy"—that is, to intentionally disrupt adjudicative proceedings in one of the two venues, even though Allergan itself had initiated proceedings in the other and could voluntarily dismiss that other action at any time.

116. The Tribe, for its part, entered the agreement for the money. The Tribe is not entering the pharmaceutical industry and, in fact, has publicly disclaimed any actual business interest in the pharmaceutical industry. *See* Saint Regis Mohawk Tribe Office of Technology, Research and Patents, *Frequently Asked Questions About New Research and Technology (Patent) Business* at 1, *available at* https://www.srmt-nsn.gov/_uploads/site_files/Office-of- Technology-Research-and-Patents-FAQ.pdf ("[T]he Tribe is not investing any money in this business. Its only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date.").

117. Licensing the second wave patents back to Allergan was not a natural outgrowth of any ownership interest the Tribe had before September 2017, and, from the

Tribe's comments, is not made pursuant to a natural future interest either. Nor was the Tribe acting in its sovereign capacity, *e.g.*, regulating the sale or use of cyclosporine on a reservation, in entering its agreement with Allergan.

118. Congress has also questioned the propriety of Allergan's transaction with the Tribe. On October 3, 2017, the Congressional Committee on Oversight and Government Reform for the House of Representatives wrote to Brent Saunders, and stated, "[t]he implications of Allergan's patent transfer raise questions for Congress as the exchange may impair competition across the pharmaceutical industry and ultimately dissuade companies from pursuing less-costly generic alternatives to brand drugs." The Committee requested documents and information from Allergan to assist the Committee in evaluating the transfer of the patents.

119. Both Allergan and the Tribe have also acted in such a way that waived the right of the Tribe to assert tribal sovereign immunity as a defense to the IPRs before the PTAB. The Tribe has asserted its tribal sovereign immunity as a basis to dismiss the IPRs pending before the PTAB. However, even though Allergan joined the Tribe as a co-plaintiff in the parallel district court case in the Eastern District of Texas, the Tribe affirmatively refrained from asserting any sovereign immunity against the invalidity challenges to the patents in that case. By virtue of being a plaintiff in the district court case, the Tribe affirmatively asserted infringement of those patents, thereby acting as a waiver of any subsequent IPR petitions for those patents. *See Ericsson Inc. v. Regents of the University of Minnesota,* IPR2017-01186, Paper 16. Even if this did not constitute a litigation waiver of the applicable tribal sovereign immunity, the Tribe nevertheless unequivocally expressed a waiver of its immunity as a defense to any challenge to the validity of the patents, in any forum, by virtue of affirmatively and expressly refraining from asserting that immunity to the invalidity challenge to the patents in the Eastern District of Texas parallel litigation.

VI. CLASS ACTION ALLEGATIONS

120. Plaintiff brings this action under Fed. R. Civ P. 23(a), (b)(2), seeking equitable and injunctive relief on behalf of a class of indirect purchasers (the "Nationwide Injunctive Relief Class") defined as follows:

> All persons or entities who purchased and/or paid for some or all of the purchase price for Restasis and/or its AB-rated generic equivalents in the United States, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period May 7, 2014 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Restasis or its generic equivalent if they paid or reimbursed some or all of the purchase price.

121. The following persons or entities are excluded from the Nationwide Injunctive Relief Class:

a. Defendant and its officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Restasis or its AB-rated generic equivalent for purposes of resale or directly from Defendant or its affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any "brand loyalist" consumers or third-party payors who purchased Restasis and who did not purchase any AB-rated generic equivalent after such generics became available;

g. Pharmacy benefit managers; and

h. The judges in this case and any members of their immediate families.

122. Plaintiff also brings this action on behalf of itself under Fed. R. Civ P. 23(a), (b)(3), seeking damages pursuant to the antitrust, unfair competition and consumer protection laws of the states and territories identified below on behalf of a class of end payor plaintiffs (the "End Payor Class") defined as follows:

> All persons or entities who purchased and/or paid for some or all of the purchase price for Restasis and/or its AB-rated generic equivalents in the United States, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period May 7, 2014 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Restasis or its generic equivalent if they paid or reimbursed some or all of the purchase price.

123. The following persons or entities are excluded from the End Payor Class:

a. Defendant and its officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Restasis or its AB-rated generic equivalent for purposes of resale or directly from Defendant or its affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any "brand loyalist" consumers or third-party payors who purchased Restasis and who did not purchase any AB-rated generic equivalent after such generics became available;

g. Pharmacy benefit managers; and

h. The judges in this case and any members of their immediate families.

124. Plaintiff also brings this action on behalf of itself under Fed. R. Civ P. 23(a), (b)(3), seeking damages pursuant to the California Cartwright Act, Cal. Bus & Prof. Code § 16700, *et seq.*, on behalf of a nationwide class of end payor plaintiffs (the "Nationwide California Law Class") defined as follows:

> All persons or entities who purchased and/or paid for some or all of the purchase price for Restasis and/or its AB-rated generic equivalents in the United States, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period May 7, 2014 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Restasis or its generic equivalent if they paid or reimbursed some or all of the purchase price.

125. The following persons or entities are excluded from the Nationwide California Law Class:

a. Defendant and its officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Restasis or its AB-rated generic equivalent for purposes of resale or directly from Defendant or its affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any "brand loyalist" consumers or third-party payors who purchased Restasis and who did not purchase any AB-rated generic equivalent after such generics became available;

g. Pharmacy benefit managers; and

h. The judges in this case and any members of their immediate families.

126. The Nationwide Injunctive Relief Class, End Payor Class, and Nationwide California Law Class are referred to collectively as the "Classes." Members of the Classes are so numerous that joinder is impracticable. Plaintiff believes that the Classes include hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

127. Plaintiff's claims are typical of the claims of the members of the Classes. Plaintiff and all members of the Classes were damaged by the same wrongful conduct of Defendant, *i.e.*, they paid, and continue to pay, artificially inflated prices for Restasis and

have been deprived of the benefits of earlier and more robust competition from cheaper generic versions of Restasis as a result of Defendant's wrongful conduct.

128. Plaintiff will fairly and adequately protect and represent the interests of the Classes. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Classes.

129. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products. Plaintiff is also represented by counsel who are registered Patent Attorneys with the PTO and who have experience litigating patent infringement allegations, particularly in *inter partes* review proceedings involving pharmaceutical patents before the PTAB.

130. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual Class members because Defendant has acted on grounds generally applicable to the Classes in their entirety. As such, overcharge damages are appropriate and injunctive and equitable relief is appropriate for the Nationwide Injunctive Relief Class.

131. Questions of law and fact common to the Classes include, without limitation:

a. Whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market.

b. Whether Allergan and the Tribe conspired to monopolize the Restasis market.

c. Whether there was any legitimate business justification for the anticompetitive contract between Allergan and the Tribe, and whether the anticompetitive effects of that contract outweigh any reasonable procompetitive benefits or justifications.

d. Whether Allergan's agreement with the Tribe violated Section 1 of the Sherman Act.

e. Whether Allergan possessed monopoly power over Restasis.

f. Whether Allergan unlawfully delayed or prevented generic manufacturers of cyclosporine ophthalmic emulsion from entering the market in the United States.

g. Whether Allergan unlawfully excluded competitors from the market for Restasis and its AB-rated generic equivalents.

h. Whether Allergan obtained the second wave patents by fraud.

i. The market for Restasis and its generic equivalents.

j. Whether the activities of Defendant as alleged herein have substantially affected interstate commerce.

k. Whether, and to what extent, Defendant's conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the Classes.

l. The appropriate injunctive and related equitable relief for the Nationwide Injunctive Relief Class.

m. The quantum of aggregate overcharge damages to the Classes.

132. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

133. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND MARKET DEFINITION

134. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can

exploit to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

135. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Restasis, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

136. Allergan and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

137. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This low price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and courts refer to as market

power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

138. Allergan had the ability to control the price of Restasis and exclude relevant competitors. Direct evidence demonstrates that: (a) generic versions of Restasis would have entered the market at substantial discounts to Restasis but for Allergan's anticompetitive conduct; (b) the gross margin on Restasis was at all times at least 60%; and (c) Allergan never lowered the price of the drugs to competitive levels in response to the pricing of other branded or generic drugs.

139. Allergan sold Restasis far in excess of marginal costs, far in excess of the competitive price, and enjoyed unusually high profit margins.

140. To the extent that Plaintiff is required to show market power indirectly, Plaintiff alleges that the relevant geographic market is the United States and its territories and possessions. The relevant product market is cyclosporine ophthalmic emulsion products for treatment of dry-eye disease, and consists of Restasis and its AB-rated generic equivalents ("cyclosporine ophthalmic emulsion product market" or "Restasis market").

141. At all relevant times, Allergan's share of the relevant market was and remains 100%.

142. At all relevant times, Allergan had monopoly power in the market for Restasis and its AB-rated generic equivalents because it had the power to maintain the price of Restasis at supra-competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Restasis, with the exception of AB-rated generic cyclosporine ophthalmic emulsion products.

143. Allergan needed to control only Restasis and its AB-rated generic equivalents, and no other products, to maintain supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to profitably maintain supra-competitive prices.

144. Restasis is not reasonably interchangeable with any products other than AB-rated generic versions of Restasis because Restasis has attributes that significantly differentiate it from other treatments for chronic dry eye disease ("DED"). The FDA does not consider Restasis and other DED treatments to be interchangeable.

145. When Allergan received FDA approval in December 2002, Allergan represented Restasis as "the first and only therapy for patients with keratoconjunctivitis sicca (chronic dry eye disease-CDED) whose tear production is presumed to be suppressed due to ocular inflammation." In its numerous filings with the FDA, Allergan has similarly insisted on Restasis' uniqueness: "RESTASIS is a pathbreaking product that was developed to treat the widespread and sometimes debilitating problem of dry eye disease. Before RESTASIS, dry eye disease was a largely unmet medical need. After years of FDA-required clinical trials, Allergan was able to produce a precisely formulated drug that has significant efficacy in treating dry eye disease." *See* Allergan, Inc., Citizen Petition, Feb. 28, 2014, at 13. Similarly, Allergan has explained that Restasis is a topical ophthalmic formulation, and "[u]nlike other drug delivery routes, a topical ophthalmic formulation usually delivers drug to the ocular tissues in relatively short timeframe of a few minutes." *See* Allergan, Inc., Comment re Docket No. FDA 2007 D 0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013, at 13.

146. Different patients may respond differently to different drugs, and even drugs within the same therapeutic class do not constrain the price of Restasis. Artificial tears offer only ephemeral relief and do nothing to address the underlying causes of dry eye. Corticosteroids can address the inflammation associated with dry eye, but have unwanted side effects, as do devices like "punctal plugs," which block the tear ducts and help the eye retain naturally produced tears for longer. Patients treated with cyclosporine would not switch to these products in response to a small but significant non-transitory increase in the price of cyclosporine in sufficient numbers to make such a price increase unprofitable. Shire US, Inc.'s introduction last year of its rival DED product, Xiidra, has

not resulted in lower Restasis prices, thus confirming Allergan's continued market power in the relevant market.

147. It may be that Allergan is also improperly using its monopoly power in the cyclosporine market to unlawfully restrain Xiidra sales. In a recently filed antitrust complaint, Shire alleges that Allergan has engaged in an "ongoing, overarching, and interconnected scheme to systematically block Shire from competing with Allergan." Compl., *Shire US, Inc. v. Allergan, Inc. et al.*, No. 2:17-cv-07716 (D.N.J. Oct. 2, 2017).

148. Allergan's ability to double the price of Restasis over the past decade without loss of significant sales further demonstrates lack of substitutability between Restasis and other drug products.

149. Restasis does not exhibit significant, positive cross-elasticity of demand with respect to price with any other DED medication. Other various DED treatments may exist, but none exhibit cross price elasticity with Restasis at competitive prices, and therefore do not constrain the price of Restasis to the competitive level. The existence of these non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise and maintain Restasis prices above the competitive level, and therefore those other drug products are not in the same relevant antitrust market as Restasis. Therapeutic alternatives, to the extent they exist, are not the same as economic alternatives.

150. Functional similarities between Restasis and other DED medications, other than AB-rated generic Restasis equivalents, are insufficient to permit inclusion of those other products in the relevant market with Restasis. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would otherwise be maintained in a competitive market. No other DED medication (except for AB-rated generic versions of Restasis) will take way sufficient sales of Restasis to prevent Allergan from raising or maintaining the price of Restasis above levels that would otherwise prevail in a competitive market.

VIII. MARKET EFFECTS AND DAMAGES TO THE CLASSES

151. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic cyclosporine ophthalmic emulsion products starting as early as May 17, 2014, when the exclusivities associated with Ding I and related patents expired. Instead, Allergan willfully and unlawfully maintained its monopoly power in the relevant market through a scheme to exclude competition. The scheme forestalled generic competition and carried out its anticompetitive effect of maintaining supra-competitive prices for Restasis. Allergan implemented its scheme by fraudulently obtaining the second wave patents, wrongfully listing these knowingly invalid patents in the Orange Book, wrongfully enforcing those patents against the generic manufacturers, submitting baseless citizen petitions to the FDA and otherwise abusing the Hatch-Waxman framework, and entering into an anticompetitive agreement with the Tribe in a blatant attempt to insulate the second wave patents from invalidation in the PTAB IPR proceedings. These acts, individually and in combination, were anticompetitive.

152. If Allergan had not defrauded the PTO, (i) the second wave patents would never have been issued, (ii) Allergan could never have used those second wave patents as a vehicle to bring suits that no reasonable pharmaceutical manufacturer in Allergan's position would expect to win predicated on knowingly invalid patents, against would-be makers of generic cyclosporine ophthalmic emulsion products, the filing of which automatically stayed any FDA final approvals of all would-be generic alternatives, and (iii) AB-rated generic Restasis manufacturers would have been able to begin marketing generic cyclosporine ophthalmic emulsion products by May 17, 2014.

153. Allergan's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Restasis from generic competition. Allergan's actions allowed it to maintain a monopoly and exclude competition in the relevant market, *i.e.*, Restasis and its AB-rated generic equivalents.

154. Allergan's exclusionary conduct has delayed generic competition and unlawfully enabled it to sell Restasis without generic competition. But for the illegal conduct of Allergan, one or more manufacturers would have begun marketing generic versions of Restasis as early as May 17, 2014.

155. The generic manufacturers seeking to sell generic Restasis have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand, and at least several of generic manufacturers would have been ready, willing, and able to market its generic version of Restasis as early as May 17, 2014 were it not for Allergan's unlawful acts.

156. Allergan's anticompetitive conduct has caused and will cause Plaintiff and the Classes to pay more than they would have paid for cyclosporine ophthalmic emulsion, absent Allergan's unlawful conduct.

157. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference branded counterpart. As a result, upon generic entry, purchases of brand drugs are rapidly substituted for generic versions of the drug for some or all purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand drug continues to lose even more market share to the generic versions of the drug.

158. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

159. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Allergan, indirect purchasers, such as Plaintiff and

members of the Classes, would have paid less for cyclosporine ophthalmic emulsion products by (a) substituting purchases of less expensive AB-rated generic Restasis for their purchases of more-expensive branded Restasis, (b) receiving discounts on their remaining branded Restasis purchases, and/or (c) purchasing Restasis at lower prices sooner.

160. Thus, Allergan's unlawful conduct deprived Plaintiff and the Classes of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

161. During the relevant period, Plaintiff and members of the Classes purchased substantial amounts of Restasis indirectly from Allergan. As a result of Allergan's unlawful anticompetitive conduct, Plaintiff and members of the Classes were compelled to pay, and did pay, artificially inflated prices for their cyclosporine ophthalmic emulsion requirements. Those prices were substantially greater than the prices that Plaintiff and members of the Classes would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Restasis was artificially inflated by Allergan's illegal conduct, and (2) class members were deprived of the opportunity to purchase lower-priced generic versions of Restasis sooner.

162. As a consequence, Plaintiff and members of the Classes have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. INTERSTATE AND INTRASTATE COMMERCE

163. At all material times, Allergan manufactured, marketed, promoted, distributed, and sold substantial amounts of Restasis in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

164. At all material times, Allergan transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous

and uninterrupted flow of commerce across state and national lines in connection with the sale of Restasis.

165. In furtherance of its efforts to restrain competition in the relevant market, Allergan employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Allergan's activities were within the flow of and have substantially affected interstate commerce.

166. Allergan's anticompetitive conduct has substantial intrastate effects in that, inter alia, retailers within each state were impaired in offering less expensive generic Restasis to end-payors inside each respective state. The impairment of competition from generic Restasis directly affects and disrupts commerce for end-payors within each state.

FIRST CLAIM FOR RELIEF

Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2: Monopolization (On behalf of Plaintiff and the Nationwide Injunctive Relief Class)

167. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

168. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

169. Allergan has willfully and unlawfully maintained its monopoly power in the cyclosporine ophthalmic emulsion product market from May 17, 2014 through at least the present day by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

170. Allergan knowingly and intentionally engaged in an anticompetitive scheme to maintain its monopoly, the components of which either standing alone or in

combination (in whole or part) were designed to and in fact have blocked and delayed entry of AB-rated generic versions of Restasis. This scheme included:

a. prosecuting serial baseless patent applications and ultimately obtaining the second wave patents by fraud through misleading the PTO and failing to exercise the duty of disclosure, candor, and good faith;

b. improperly listing the second wave patents in the Orange Book;

c. engaging in multiple sham litigations;

d. submitting serial sham citizen petitions; and

e. abusing the PTAB's IPR process through the sham transfer of the second wave patents to the Saint Regis Mohawk Tribe.

171. Allergan knowingly and intentionally committed fraud under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), to induce the PTO to grant the second wave patents. Specifically, Allergan—after repeated denials of prior substantially similar serial applications over more than a 10-year period—submitted sworn declarations in 2013, that Allergan characterized, by commission and omission, as presenting new data that showed surprising results not anticipated by prior art (*i.e.*, Ding I), when in fact the data presented were neither new nor surprising. Had Allergan made clear to the PTO examiner that the 2013 declaration's statements and data were lifted from prior art known to Allergan for over 10 years, as Allergan's duty of disclosure, candor, and good faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art. Allergan's misstatements were material, fraudulent, and made knowingly and with the intent to deceive, and in fact induced the PTO to issue the second wave patents.

172. Allergan knew when it submitted the second wave patents for listing in the Orange Book that these patents were fraudulently procured and/or were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that therefore the second wave patents should not have been listed in the Orange Book.

Allergan knew that the listing of the second wave patents in the Orange Book would force ANDA applicants to file paragraph IV certifications that would thereby provide Allergan the opportunity to file patent infringement suits against those ANDA applicants. Allergan knew that its lawsuits, however baseless, would trigger an automatic stay of FDA final approval of any pending paragraph IV-certified ANDA applicant's generic Restasis product for a period of 30 months—or longer if a court so ordered.

173. Allergan also knew that the listing of the second wave patents in the Orange Book would create confusion regarding any ANDA first-filer status and therefore chill the FDA's ANDA approval process because such Orange Book listing invariably would result in a different order of responsive ANDA certifications that until then had certified only as to the Ding I and related patents, which had previously been the only patents listed in the Orange Book for Restasis. Such prior certifications included paragraph II or III certifications on generic cyclosporine products that were intended to be marketed only after expiration of the Ding I and related patents in May 2014. Unlike paragraph IV certifications, such paragraph II or III certifications did not trigger any stay of the FDA's approval process. Accordingly, absent the listing in the Orange Book of the second wave patents, there was no way to effectuate any stay of the FDA's final approval of any previously paragraph II– or III–certified ANDA.

174. Allergan knowingly and intentionally engaged in multiple sham litigations against manufacturers of AB-rated generic equivalents of Restasis. Allergan intentionally and deceptively alleged the generic manufacturers' products infringed its second wave patents, knowing when those suits were filed that those Patents were wrongfully obtained though fraud on the PTO and were otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew, at the time those multiple sham suits were filed, that it had no realistic likelihood of success; that is, that there was no realistic likelihood that a court would enforce the fraudulently obtained and otherwise invalid second wave patents against a generic company. Allergan knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a

chance of succeeding on the merits of these infringement lawsuits. Allergan filed these sham lawsuits to use a government process as an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly, regardless of any actual merit in its infringement claims.

175. Allergan knowingly and intentionally submitted multiple and serial sham citizen and other petitions to the FDA to delay FDA approval of any of the pending generic ANDA applications, regardless of any objective merit to any part of any petition. Allergan also knew that its citizen petitions would further any first-filer confusion it had already created through its Orange Book listing, which independently impeded the FDA's ANDA approval process.

176. Allergan knowingly and intentionally transferred the second wave patents to the Saint Regis Mohawk Tribe—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind—in a bald attempt to evade invalidation of those patents and cessation of its cyclosporine ophthalmic emulsion product monopoly.

177. By means of this scheme, Allergan intentionally and wrongfully maintained monopoly power with respect to cyclosporine ophthalmic emulsion products in violation of Section 2 of the Sherman Act. 15 U.S.C. § 2. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Nationwide Injunctive Relief Class paid artificially inflated prices for their cyclosporine ophthalmic emulsion products.

SECOND CLAIM FOR RELIEF

Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2: Attempted Monopolization (On Behalf of Plaintiff and the Nationwide Injunctive Relief Class)

178. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

179. Allergan attempted to monopolize the market for cyclosporine ophthalmic emulsion products in violation of Section 2 of the Sherman Act based on the anticompetitive conduct described herein.

180. Allergan had a specific intent to monopolize the market for cyclosporine ophthalmic emulsion products. As discussed in more detail above, Allergan specifically engaged in a wide range of baseless petitions to wrongfully block anyone from selling generic cyclosporine ophthalmic emulsion in the United States. In doing so, Allergan attempted to control high prices in the relevant market, and to exclude competition.

181. Through the anticompetitive and exclusionary acts described above, Allergan achieved a dangerous probability of success of monopolizing the relevant market. By excluding generic entrants, Allergan maintained its 100% market share and significant pricing power over cyclosporine ophthalmic emulsion products for the treatment of dry-eye disease in the United States. As a result, Allergan was able to charge a higher price for Restasis than it otherwise would have absent its unlawful conduct and Plaintiff and members of the Class paid, and continue to pay, supra-competitive prices for cyclosporine ophthalmic emulsion products as a result.

THIRD CLAIM FOR RELIEF

Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2: Conspiracy to Monopolize (On behalf of Plaintiff and the Nationwide Injunctive Relief Class)

182. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

183. Allergan conspired with the Saint Regis Mohawk Tribe (the "Tribe"), through their anticompetitive ownership transfer and licensing agreement (the "Agreement"), to monopolize the market for cyclosporine ophthalmic emulsion products in violation of Section 2 of the Sherman Act based on the anticompetitive conduct described herein.

184. Allergan and the Tribe are separate and distinct entities; neither is a subsidiary or agent of the other. Apart from their agreement discussed herein, Allergan and the Tribe are economically independent from each other.

185. Allergan had a specific intent to monopolize. Allergan specifically intended to use the agreement with the Tribe to invoke the Tribe's sovereign immunity to protect the second wave patents before the Patent Trial and Appellate Board in its Inter Partes Reviews. Protecting Allergan's invalid and fraudulently obtained patents in the IPR process has already further delayed generic entry into the relevant market.

FOURTH CLAIM FOR RELIEF

Violations of Sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1, 3: Agreement to Unreasonably Restrain Trade (On Behalf of Plaintiff and the Nationwide Injunctive Relief Class)

186. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

187. Allergan's anticompetitive ownership transfer and licensing agreement (the "Agreement") with the Tribe as set forth in this Complaint has violated Sections 1 and 3 of the Sherman Act. 15 U.S.C. §§ 1, 3.

188. Allergan and the Tribe are separate and distinct entities; neither is a subsidiary or agent of the other. Apart from the Agreement, Allergan and the Tribe are economically independent from each other.

189. Allergan and the Tribe have acted in concert during the proceedings before the PTAB.

190. Allergan and the Tribe entered their conspiracy with the purpose and effect of restraining competition in the relevant market.

191. During the Class Period, Allergan had market power in the market for cyclosporine ophthalmic emulsion. The Tribe was only a participant in this market insofar as Allergan could use it as a conduit to protect Allergan's market share through baseless assertions of sovereign immunity.

192. Allergan and the Tribe's conspiracy had no procompetitive benefits; it did nothing to increase competition in the market for cyclosporine ophthalmic emulsion products. It instead inflicted substantial competitive harms, namely by preventing entry by generics and raising the price of Restasis beginning no later than September 8, 2017.

193. Allergan and the Tribe affected interstate commerce by keeping the price of cyclosporine ophthalmic emulsion products higher than they would be absent their unlawful restraint of trade.

FIFTH CLAIM FOR RELIEF

For Monopolization Under State Law for *Walker Process* Fraud (On behalf of Plaintiff and the End Payor Class)

194. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

195. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

196. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by wrongfully asserting patents obtained by fraud to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

197. Allergan knowingly and intentionally asserted the invalid second wave patents to maintain its monopoly power. This was intended to, and in fact had the effect of, blocking and delaying entry of AB-rated generic versions of Restasis.

198. Allergan, by and through its patent attorneys and scientists who submitted declarations in support of patentability (including Laura L. Wine, Dr. Rhett M. Schiffman, and Dr. Mayasa Attar), made misrepresentations of fact to the Patent and Trademark Office. These included:

a. Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "surprisingly, the claimed formulation demonstrated a 8-fold increase in relative efficacy for the Schirmer Teat Test score in the first study of Allergan's Phase 3 trials compares to the relative efficacy for the . . . formulation discussed in Example 1E of Ding, tested in Phase 2 trials . . . . This was clearly a very surprising and unexpected result."

b. Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed ". . . the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the . . . formulation tested in Phase 2 and disclosed in Ding. This was clearly a very surprising and unexpected result."

c. Figures 1-4 in Dr. Schiffman's declaration reported figures from the Sall paper but omitted all error bars and p-values. In truth, as the Court later found, none of the pair-wise comparisons between the two cyclosporine formulations for corneal staining and Schirmer scores in the Phase 2 study or the pooled Phase 3 studies demonstrated statistical significance at any time point, and many of the p-values for the pair-wise comparisons were very high. The actual statistical analyses showed that any observed difference in raw numbers between the cyclosporine formulations was likely the result of random chance.

d. Dr. Schiffman did not disclose to the PTO that he was comparing different Schirmer tear test scores—one without anesthesia in Phase 2 and one with anesthesia in Phase 3—to purportedly show a difference in efficacy. As the Court later found, only the Schirmer tear test results with anesthesia in Phase 3 significantly favored the 0.05% cyclosporine formulation. "It was therefore only by comparing the results of two different types of tests that Dr. Schiffman was able to produce a significantly distorted picture suggesting that the [Phase 3 formulation' was much more effective than the [Phase 2 formulation]. This was both statistically and clinically improper."

e. Dr. Schiffman did not disclose to the PTO that the method he chose to calculate the differences in efficacy "exaggerated the difference in the raw values between the two."

f. The calculations in Dr. Schiffman's table are misleading: (1) Dr. Schiffman used ratios of the degree of improvement, which tends to overstate the difference between the results; (2) Dr. Schiffman ignored the fact that the Phase 2 study was quite small, and that the difference in the raw numbers between formulations were not statistically significant; and (3) Dr. Schiffman only included data from favorable comparisons between the two formulations. He omitted categories where the Ding I formulation did better than the second wave formulation.

g. Dr. Schiffman did not tell the PTO that the data provided was taken from the Sall paper published more than a dozen years earlier (and three years before the priority date for the Restasis patents). Even if the results presented were surprising (they were not), they were publicly known before the date of invention and cannot be the basis for a claim that it was "unexpected" as of the Restasis patent's priority date.

199. These representations were material. The examiner had repeatedly rejected the applications as obvious before Allergan's misleading statements and omissions. The examiner had also earlier rebuffed Allergan's purported secondary considerations of non-obviousness (including commercial success and unmet need). The PTAB's later decision, as well as the Eastern District of Texas' later decision, support the materiality of these misrepresentations and omissions.

200. Allergan made these statements with intent to deceive the PTO. The misleading statements were made intentionally, not accidentally. Allergan was motivated to obtain a longer period of patent protection, given the large sales of Restasis and the importance of the product to the company. The misleading statements were only made after the examiner rejected the application (not with the initial filing) and were made to overcome a rejection and support patentability. There is no innocent explanation for presenting the information as it was presented in the misleading declaration and

accompanying submissions; the only reasonable inference is that Allergan intended to deceive the PTO.

201. The PTO reasonably relied on Allergan's false and misleading statements in issuing the second wave patents. The examiner stated that the Schiffman declaration was deemed sufficient to overcome his earlier rejection based on Ding I because "Examiner is persuaded that, unexpectedly, the claimed formulation . . . demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Phase 3 trials compared to relative efficacy for the formulation disclosed in Ding I." The Examiner also explained that the declarations "illustrate that the claimed formulations . . . also demonstrate a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compare to the . . . formulation tested in Phase 2 and disclosed in Ding . . .."

202. But for Allergan's misrepresentations and omissions, the second wave patents would not have issued. Had they not issued, there was no patent-based impediment to generic versions of Restasis entering the market from May 17, 2014 onwards.

203. Allergan listed the second wave patents in the Orange Book and later asserted them against all would-be generic competitors.

204. But for Allergan's asserting the fraudulently obtained patent, generic versions of Restasis would have been available as early as May 17, 2014, and in any case within the Class Period.

205. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

206. By engaging in the foregoing conduct, Allergan has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Ala. Code § 6-5-60 with respect to purchases in Alabama by members of the Class.

b. Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law with respect to purchases in California by members of the Class.

d. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

f. Haw. Rev. Stat. §§ 480-1, *et seq.*, with respect to purchases in Hawaii by members of the Class

g. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases in Illinois by members of the Class.

h. Iowa Code § 5531 *et seq.*, with respect to purchases in Iowa by members of the Class.

i. Kansas Stat. Ann. § 50-101 et seq., with respect to purchases in Kansas by members of the Class.

j. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

k. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class.

o. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to purchases in Nevada by members of the Class.

r. N.H. Rev. Stat. Ann. §§ 356.1, with respect to purchases in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law § 340 ("The Donnelly Act"), with respect to purchases in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1, *et seq.*, with respect to purchases in North Dakota by members of the Class.

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

x. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

y. R.I. Gen. Laws §§ 6-36-1 *et seq.,* with respect to purchases in Rhode Island by members of the Class.

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class.

aa. Tenn. Code Ann §§ 47-25-101, *et seq.,* with respect to purchases in Tennessee by members of the Class.

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class.

cc. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

dd. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class.

ee. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

207. Plaintiff and members of the End Payor Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for cyclosporine ophthalmic emulsion products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

208. Plaintiff and the End Payor Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

SIXTH CLAIM FOR RELIEF

Monopolization Under State Law for Allegations of an Overarching Anticompetitive Scheme (On behalf of Plaintiff and the End Payor Class)

209. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

210. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

211. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

212. Allergan knowingly and intentionally engaged in an anticompetitive scheme to maintain its monopoly power, the components of which either standing alone or in combination (in whole or part) were designed to and in fact have blocked and delayed entry of AB-rated generic versions of Restasis. This scheme included:

a. Prosecuting serial baseless patent applications and ultimately obtaining the second wave patents by fraud through misleading the PTO and failing to exercise the duty of disclosure, candor, and good faith;

b. Improperly listing the second wave patents in the Orange Book;

c. Wrongfully trying to enforce the second wave patents in multiple lawsuits.

d. Submitting serial baseless citizen petitions; and

e. Abusing the Patent Trial and Appeal Board's *inter partes* review process through an anticompetitive transfer of the second wave patents to the Saint Regis Mohawk Tribe.

213. Allergan knowingly and intentionally committed *Walker Process* fraud to induce the PTO to grant the second wave patents. Specifically, Allergan—after repeated denials of prior substantially similar serial applications over more than a 10-year period—submitted false sworn declarations in 2013, that Allergan characterized, by commission and omission, as presenting new data that showed surprising results not anticipated by

prior art (*i.e.*, Ding I), when in fact the data presented was neither new nor surprising. Had Allergan made clear to the PTO examiner that the 2013 declarations statements and data were lifted from prior art known to Allergan for over 10 years, as Allergan's Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art. Allergan's misstatements were material, fraudulent, and made knowingly and with the intent to deceive, and in fact induced the PTO to issue the second wave patents.

214. Allergan knew when it listed the second wave patents in the Orange Book that these patents were fraudulently procured and/or were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that therefore the second wave patents should not have been listed in the Orange Book. Allergan knew that listing the second wave patents in the Orange Book would force ANDA applicants to file paragraph IV certifications that would thereby provide Allergan the opportunity to file patent infringement suits against those ANDA applicants that, regardless of the baselessness of such suit, would trigger an automatic stay of FDA approval for a period of up to 30 months.

215. Allergan knowingly and intentionally engaged in multiple sham litigations against manufacturers of AB-rated generic equivalents of Restasis that no reasonable pharmaceutical company in Allergan's position would realistically expect to win. Allergan intentionally and deceptively alleged the generic manufacturers' products infringed its second wave patents, knowing when those suits were filed that such patents were wrongfully obtained though fraud on the PTO and were otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew, at the time those multiple sham suits were filed, that it had no realistic likelihood of success; that is, that there was no realistic likelihood that a court would enforce the fraudulently-obtained and otherwise invalid second wave patents against a generic company. Allergan knew, therefore, that no reasonable pharmaceutical manufacturer

would have believed it had a reasonable chance of succeeding on the merits of these infringement lawsuits. Allergan filed these sham lawsuits for the purposes of using a governmental process to harm competition and to keep generics off the market and wrongfully maintain its monopoly power over Restasis, regardless of any actual merit to its infringement claims.

216. Allergan knowingly and intentionally submitted multiple and serial citizen and other petitions to the FDA when no reasonable pharmaceutical manufacturer in Allergan's position would expect the FDA to grant the requested relief. The purpose and intent of was to delay the FDA's approval of any of the pending generic ANDA applications, regardless of any objective merit to any part or parts of any petition.

217. Allergan knowingly and intentionally transferred the second wave patents to the Tribe—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind and is better known for its operation of casinos on tribal lands in New York—in an attempt to evade invalidation of those patents and cessation of its Restasis monopoly, which illustrates the extraordinary measures Allergan was willing to take in its stop-at-nothing desperation to delay competition.

218. Allergan's anticompetitive conduct as alleged herein is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine.

219. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

220. By engaging in the foregoing conduct, Allergan has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Ala. Code § 6-5-60 with respect to purchases in Alabama by members of the Class.

b. Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law with respect to purchases in California by members of the Class.

d. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

f. Haw. Rev. Stat. §§ 480-1, *et seq.*, with respect to purchases in Hawaii by members of the Class

g. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases in Illinois by members of the Class.

h. Iowa Code § 5531 *et seq.*, with respect to purchases in Iowa by members of the Class.

i. Kansas Stat. Ann. § 50-101 et seq., with respect to purchases in Kansas by members of the Class.

j. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

k. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class.

o. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to purchases in Nevada by members of the Class.

r. N.H. Rev. Stat. Ann. §§ 356.1, with respect to purchases in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law § 340 ("The Donnelly Act"), with respect to purchases in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1, *et seq.*, with respect to purchases in North Dakota by members of the Class.

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

x. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

y. R.I. Gen. Laws §§ 6-36-1 *et seq.,* with respect to purchases in Rhode Island by members of the Class.

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class.

aa. Tenn. Code Ann §§ 47-25-101, *et seq.,* with respect to purchases in Tennessee by members of the Class.

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class.

cc. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

dd. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class.

ee. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

221. Plaintiff and members of the End Payor Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

222. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

SEVENTH CLAIM FOR RELIEF

For Conspiracy in Restraint of Trade Under State Law Against Allergan (On behalf of Plaintiff and the End Payor Class)

223. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

224. Defendant entered into a contract with the Tribe in unreasonable restraint of trade.

225. Defendant's contract in restraint of trade and its other anticompetitive acts were intentionally directed at the Restasis market, and had a substantial and foreseeable effect on interstate commerce by interfering with potential generic competition for Restasis and raising and maintaining Restasis prices at supra-competitive levels throughout the United States.

226. As a result, Allergan and the Tribe have effectively excluded competition from the Restasis market, allowing Allergan to unlawfully maintain its monopoly in the

Restasis market, and both Allergan and the Tribe have profited from their illegal contract by maintaining prices at artificially high levels.

227. There is no legitimate business justification for the anticompetitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market, including the contract between Allergan and the Tribe. The anticompetitive effects of Allergan's and the Tribe's contract far outweigh any conceivable pro-competitive benefit or justification.

228. By engaging in the foregoing conduct, Defendant has intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state laws:

a. Ala. Code § 6-5-60 with respect to purchases in Alabama by members of the Class.

b. Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law with respect to purchases in California by members of the Class.

d. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

f. Haw. Rev. Stat. §§ 480-1, *et seq.*, with respect to purchases in Hawaii by members of the Class

g. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases in Illinois by members of the Class.

h. Iowa Code § 5531 *et seq.*, with respect to purchases in Iowa by members of the Class.

i. Kansas Stat. Ann. § 50-101 et seq., with respect to purchases in Kansas by members of the Class.

j. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

k. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class.

o. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to purchases in Nevada by members of the Class.

r. N.H. Rev. Stat. Ann. §§ 356.1, with respect to purchases in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law § 340 ("The Donnelly Act"), with respect to purchases in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1, *et seq.*, with respect to purchases in North Dakota by members of the Class.

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

x. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

y. R.I. Gen. Laws §§ 6-36-1 *et seq.,* with respect to purchases in Rhode Island by members of the Class.

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class.

aa. Tenn. Code Ann §§ 47-25-101, *et seq.,* with respect to purchases in Tennessee by members of the Class.

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class.

cc. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

dd. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class.

ee. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

229. Plaintiff and members of the End Payor Class have been injured in their business or property by reason of Defendant's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Defendant's conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

230. Plaintiff and the End Payor Class seek damages and multiple damages as permitted by law for their injuries by Defendant's violations of the aforementioned statutes.

EIGHTH CLAIM FOR RELIEF

For Conspiracy in Restraint of Trade Under the California Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 *et seq.* (On behalf of Plaintiff and the Nationwide California Law Class)

231. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

232. Defendant entered into a contract with the Tribe in unreasonable restraint of trade.

233. Defendant's contract in restraint of trade and its other anticompetitive acts were intentionally directed at the United States Restasis market, and had a substantial and foreseeable effect on interstate commerce by interfering with potential generic competition for Restasis and raising and maintaining Restasis prices at supra-competitive levels throughout the United States.

234. As a result of the contract in restraint of trade, Allergan and the Tribe have effectively excluded competition from the Restasis market, allowing Allergan to unlawfully maintain its monopoly in the Restasis market, and both Allergan and the Tribe have profited from their illegal contract by maintaining prices at artificially high levels.

235. There is no legitimate business justification for the anticompetitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market, including the contract between Allergan and the Tribe. The anticompetitive effects of Allergan's and the Tribe's contract far outweigh any conceivable pro-competitive benefit or justification.

236. By engaging in the foregoing conduct, Defendant has intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the California Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*

237. Plaintiff and members of the Nationwide California Law Class have been injured in their business or property by reason of Defendant's antitrust violations alleged

in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Defendant's conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

238. Plaintiff and the Nationwide California Law Class seek damages and multiple damages as permitted by law for their injuries by Defendant's violations of the Cartwright Act.

239. Application of California antitrust law to the Nationwide California Law Class is appropriate. Allergan maintained its headquarters in Irvine, California during most of the relevant period. It conducted much of the challenged behavior from its California headquarters. California has a large population and it was therefore foreseeable that a substantial number of California purchasers would be impacted by Allergan's unlawful conduct.

NINTH CLAIM FOR RELIEF

For Conspiracy to Monopolize Under State Law (On behalf of Plaintiff and the End Payor Class)

240. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

241. Allergan and the Tribe have conspired to allow Allergan to willfully maintain and unlawfully exercise monopoly power in the Restasis market through the anticompetitive contract with the specific intent to monopolize the Restasis market, and preventing competition in the market.

242. As a result of the conspiracy, Allergan and the Tribe have effectively excluded competition from the Restasis market, unlawfully maintained Allergan's monopoly in the Restasis market, and profited from their anticompetitive conduct by maintaining prices at artificially high levels.

243. As a result of the contract in restraint of trade, Allergan and the Tribe have effectively excluded competition from the Restasis market, allowing Allergan to unlawfully maintain its monopoly in the Restasis market, including the contract between Allergan and the Tribe. The anticompetitive effects of Allergan's and the Tribe's contract far outweigh any conceivable pro-competitive benefit or justification.

244. There is no legitimate business justification for the anticompetitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market. The anticompetitive effects of Allergan's and the Tribe's agreement far outweigh any conceivable pro-competitive benefit or justification.

245. By engaging in the foregoing conduct, Defendant has intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of the following state laws:

a. Ala. Code § 6-5-60 with respect to purchases in Alabama by members of the Class.

b. Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law with respect to purchases in California by members of the Class.

d. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

f. Haw. Rev. Stat. §§ 480-1, *et seq.*, with respect to purchases in Hawaii by members of the Class

g. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases in Illinois by members of the Class.

h. Iowa Code § 5531 *et seq.*, with respect to purchases in Iowa by members of the Class.

i. Kansas Stat. Ann. § 50-101 et seq., with respect to purchases in Kansas by members of the Class.

j. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

k. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class.

o. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to purchases in Nevada by members of the Class.

r. N.H. Rev. Stat. Ann. §§ 356.1, with respect to purchases in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law § 340 ("The Donnelly Act"), with respect to purchases in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1, *et seq.*, with respect to purchases in North Dakota by members of the Class.

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

x. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

y. R.I. Gen. Laws §§ 6-36-1 *et seq.,* with respect to purchases in Rhode Island by members of the Class.

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class.

aa. Tenn. Code Ann §§ 47-25-101, *et seq.,* with respect to purchases in Tennessee by members of the Class.

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class.

cc. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

dd. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class.

ee. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

246. Plaintiff and members of the Class have been injured in their business or property by reason of Defendant's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Defendant's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

247. Plaintiff and the End Payor Class seek damages and multiple damages as permitted by law for their injuries by Defendant's violations of the aforementioned statutes.

TENTH CLAIM FOR RELIEF

Unjust Enrichment Under State Law (On behalf of Plaintiff and the End Payor Class)[2]

248. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

249. Defendant has benefited from substantially increased profits as a result of its unlawful conduct.

250. Defendant's financial benefits resulting from its unlawful and inequitable conduct are traceable to overpayments for Restasis by Plaintiff and members of the Class.

251. Plaintiff and the Class have conferred upon Defendant an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

252. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Restasis, as those intermediaries are not liable and would not compensate Plaintiff or the Class for damages caused by the unlawful conduct of Defendant.

253. The economic benefit of overcharges and unlawful monopoly profits derived by Defendant through charging supra-competitive and artificially inflated prices for Restasis is a direct and proximate result of Defendant's unlawful practices.

254. The financial benefits derived by Defendant rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendant.

255. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Defendant to be permitted to retain

[2] Plaintiff alleges unjust enrichment claims under the laws of all States (except Ohio and Indiana) as well as the District of Columbia, Puerto Rico and the U.S. Virgin Islands.

any of the overcharges for Restasis derived from Defendant's unfair and unconscionable method, acts, and trade practices alleged in this Complaint.

256. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds that it derived from its anticompetitive scheme.

257. A constructive trust should be imposed upon all unlawful or inequitable sums received Defendant traceable to Plaintiff and the End Payor Class.

258. Plaintiff and the End Payor Class have no adequate remedy at law.

ELEVENTH CLAIM FOR RELIEF

Unfair and Deceptive Trade Practices Under State Law (On behalf of Plaintiff and the End Payor Class)

259. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

260. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendant's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and Class members were deprived of the opportunity to purchase a generic version of Restasis and forced to pay higher prices.

261. There was and is a gross disparity between the price that Plaintiff and the Class members paid and for the brand Restasis product and the value received, given that a much cheaper substitute generic product should have been available sooner and in greater quantity, and prices for brand Restasis should have been much lower, but for Defendant's unlawful conduct.

262. By engaging in the foregoing conduct, Defendant has engaged in unfair competition or deceptive acts and practices in violation of the following state laws:

a. Alaska Statute § 45.50.471, *et seq.*, with respect to purchases in Alaska by members of the Class.

b. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by members of the Class.

c. Ariz. Code §§ 44-1255, *et seq.*, with respect to purchases in Arizona by members of the Class.

d. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class.

e. Colo. Rev. Stat. § 6-1-101, *et seq.*, with respect to the purchases in Colorado by members of the Class.

f. 6 Del. Code § 2511, *et seq.*, with respect to purchases in Delaware by members of the Class.

g. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases in the District of Columbia by members of the Class.

h. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

i. Ga. Code § 10-1-370, with respect to purchases in Georgia by members of the Class.

j. Haw. Rev. Stat. Ann. § 480-1, *et seq.*, with respect to purchases in Hawaii by members of the Class.

k. Kan. Stat. §§ 50-623, *et seq.*, with respect to the purchases in Kansas by members of the Class.

l. Idaho Code §§ 48-601, *et seq.*, with respect to the purchases in Idaho by members of the Class.

m. 815 ILCS §§ 505/1, *et seq.*, with respect to the purchases in Illinois by members of the Class.

n. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the purchases in Maine by members of the Class.

o. Mass. Ann. Laws ch. 93A, § 1, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

p. Mich. Comp. Laws Ann. §§ 445.903, *et seq.*, with respect to purchases in Michigan by members of the Class.

q. Minn. Stat. §§ 325D.43, *et seq*, with respect to purchases in Minnesota by members of the Class.

r. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases in Missouri by members of the Class.

s. Mont. Code § 30-14-103, *et seq.*, and §30-14-201, *et seq.* with respect to purchases in Montana by members of the Class

t. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases in Nebraska by members of the Class.

u. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases in Nevada by members of the Class.

v. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases in New Hampshire by members of the Class.

w. N.J. Stat. § 56-8-1, *et seq.*, with respect to purchases in New Jersey by members of the Class

x. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases in New Mexico by members of the Class.

y. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases in New York by members of the Class.

z. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

aa. N.D. Cent. Code § 51-15-01, *et seq.*, with respect to purchases in North Dakota by members of the Class.

bb. Or. Rev. Stat. §§ 646.605, *et seq.,* with respect to purchases in Oregon by members of the Class.

cc. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases in Pennsylvania by members of the Class.

dd. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases in Rhode Island by members of the Class.

ee. S.C. Code Ann. § 39-5-10, *et seq.*, with respect to purchases in South Carolina by members of the Class.

ff. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases in South Dakota by members of the Class.

gg. Tenn. Code §§ 47-18-101, *et seq.,* with respect to purchases in Tennessee by members of the Class.

hh. Utah Code §§13-11-1, *et seq.*, with respect to purchases in Utah by member of the Class.

ii. Vt. Stat Ann. 9, § 2451, *et seq.*, with respect to purchases in Vermont by member of the Class.

jj. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases in Virginia by members of the Class.

kk. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases in West Virginia by members of the Class.

ll. Wisc. Stat. § 100.18, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

mm. U.S. Virgin Islands Consumer Fraud and Deceptive Business Practices Act, 12A V.I.C. §§ 102, 301-35, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

263. Plaintiff and members of the End Payor Class have been injured in their business and property by reason of Defendant's anticompetitive, unfair or deceptive acts alleged in detail above. Their injury consists of paying higher prices for Restasis than they would have paid in the absence of these violations, and being denied the opportunity to purchase the cheaper generic Restasis. These injuries are of the type the state consumer protection and unfair business practices statutes were designed to prevent and directly result from Defendant's unlawful conduct.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Classes, demands judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes and declare the Plaintiff representative of the Nationwide Injunctive Class, End Payor Class, and Nationwide California Law Class;

B. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

C. Enter judgment against Defendant in favor of Plaintiff and the Classes;

D. Enter a judgment granting injunctive and equitable relief against Defendant and in favor of Plaintiff and the Nationwide Injunctive Relief Class;

E. Award damages to the End Payor Class and Nationwide California Law Class and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

F. Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

G. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendant, and as the Court deems just.

XII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

Dated: January 5, 2018

Respectfully Submitted,
JOSEPH SAVERI LAW FIRM, INC.

By: *_/s/ Joseph R. Saveri_*
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